Abbott Laboratories

Abbott Diabetes Care
1380 South Loop Road.
Alameda, CA 94502

K062770

DEC 14 2006

510(k) Summary

General Information

Submitter Information	Abbott Diabetes Care Inc. 1360 South Loop Road Alameda, CA 94502
Contact Person:	Mary Rose Regulatory Affairs Supervisor
Telephone No.:	510.239.2634
Fax No.	510.864.4770
Date Prepared	October 26, 2006
Device Information:	
Proprietary Name:	CoPilot™ Health Management System
Common Name:	Data Management Software
Predicate Device:	Precision Link™ Diabetes Data Management System (cleared 3/25/2004, under K040628)

Device Description

The CoPilot™ Health Management System is a PC-based software application that permits people with diabetes, their healthcare team, and caregivers to upload data from FreeStyle and Precision Blood Glucose Monitoring Systems into the CoPilot System. The CoPilot™ Health Management System is intended for use in home and clinical settings to upload data from these devices to a patient's or healthcare professional's computer where the data may be saved, displayed in a number of formats, printed, or exported to an authorized user.

Intended Use

The CoPilot™ Health Management System is intended for use in the home and clinical settings by people with diabetes and healthcare professionals as an aid in the review, analysis and evaluation of historical glucose test results in support of an effective diabetes management program.

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Technological Characteristics

The CoPilot Health Management System software is a data acquisition and storage application used for diabetes data management. The CoPilot software features three main data functions of data entry, reports, and synchronization.

CoPilot Health Management System software operates in a Microsoft Windows Operating System platform. The software allows the user to display a variety of graphs and statistics based on user-selectable date intervals, time of day segments, and blood glucose target ranges.

Performance Data

The CoPilot™ Health Management System software has been developed in accordance with the FDA's *Guidance for the Content of Premarket Submission for Medical Devices Containing Software* (May 11, 2005) and General *Principles of Software Validation 1/11/2002: Final Guidance for Industry and FDA Staff,* where applicable and appropriate.

Software, Software QA, and System verification testing demonstrates that the CoPilot™ Health Management System meets the performance requirements for the intended use of the system.

Non-clinical/Clinical Conclusions

Results of non-clinical and clinical testing demonstrate that the performance of the CoPilot™ Health Management System is acceptable and comparable to the performance and safety characteristics of the predicate device when used according to its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 16 2007

Ms. Mary Rose
Regulatory Affairs Supervisor
Abbott Diabetes Care, Inc.
1360 South Loop Road
Alameda, CA 94502

Re: k062770
Trade/Device Name: CoPilot Health Management System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW
Dated: September 14, 2006
Received: September 18, 2006

Dear Ms. Rose:

This letter corrects our substantially equivalent letter of December 14, 2006.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k062770

Device Name: CoPilot™ Health Management System

Indications For Use:

The CoPilot™ Health Management System is intended for use in the home and clinical settings by people with diabetes and healthcare professionals as an aid in the review, analysis and evaluation of historical glucose test results in support of an effective diabetes management program.

Prescription Use _____ AND/OR Over-The-Counter Use ___X___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K062770